Stereotactic **A**blative **F**ractionated **R**adiotherapy versus Radiosurgery for **O**ligometastatic **N**eoplasia to the Lung: A Randomized Phase II Trial

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Disclosures

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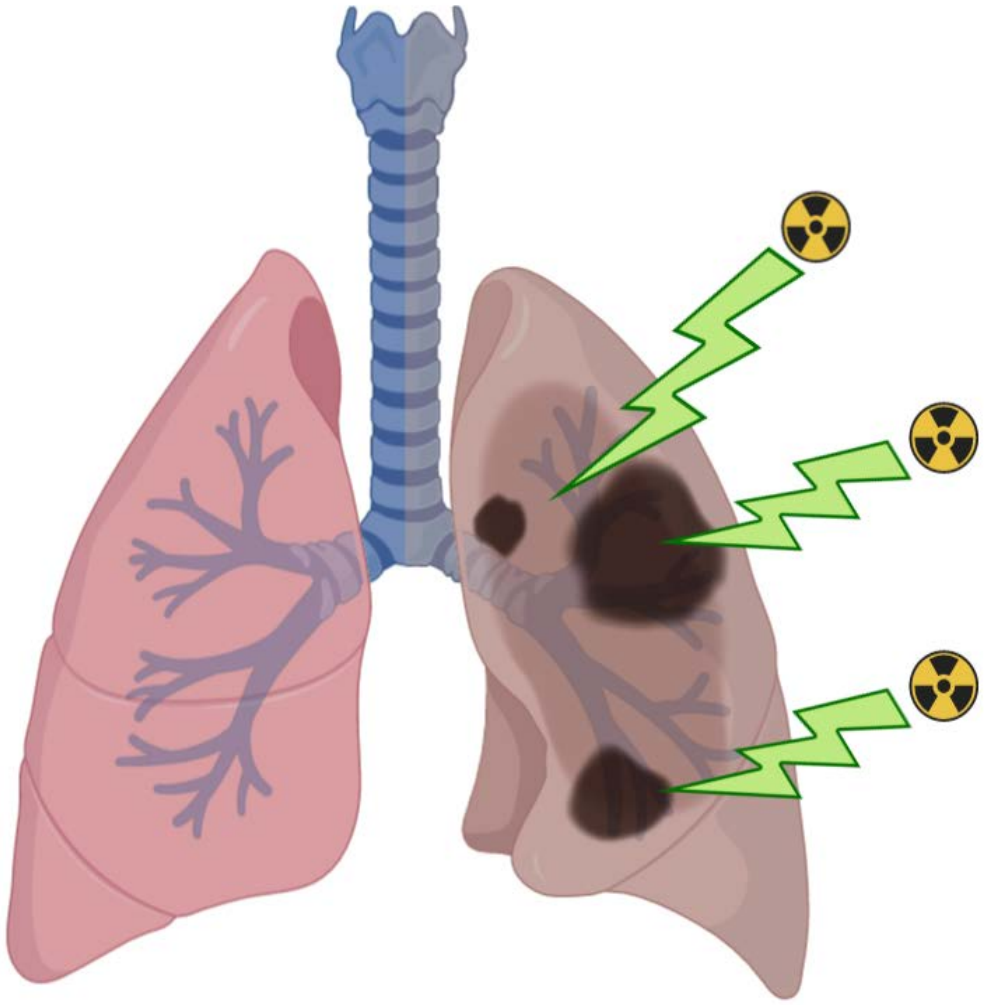
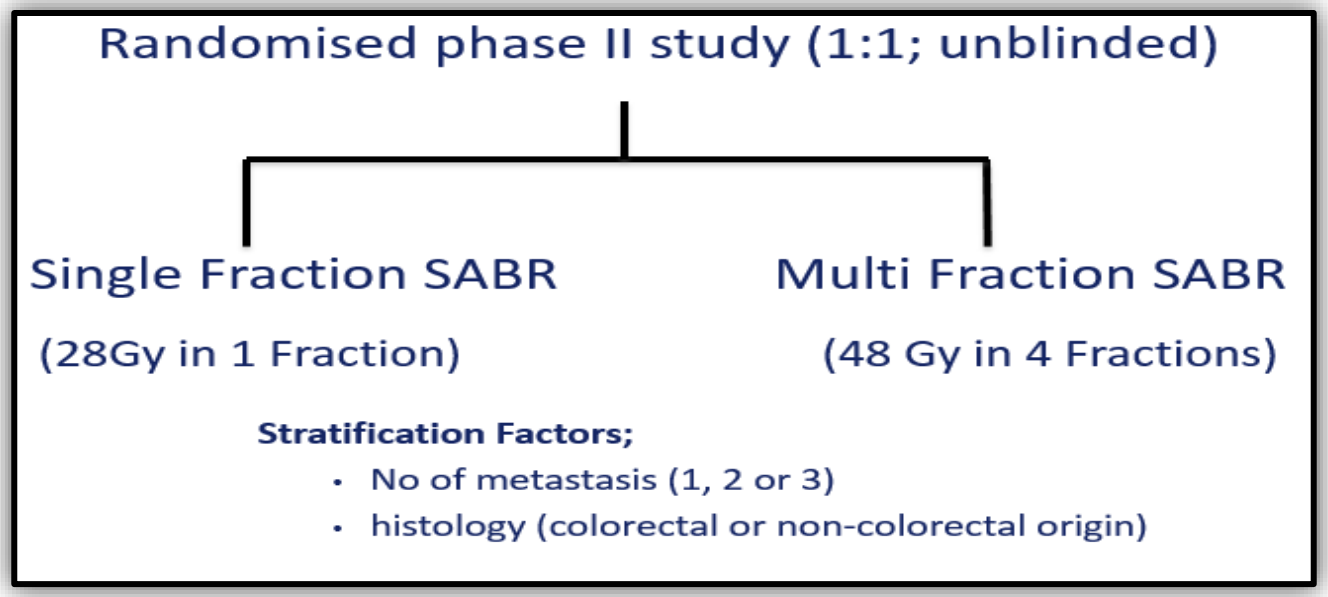
Background: Why this Trial?

- The lung is the second most common place for cancer to spread
- Most patients are treated with lifelong anti-cancer drug therapy only, with little prospect for long term cancer control
- Some patients have limited spread to the lungs, and may be suitable for surgery (invasive) or Stereotactic body radiotherapy (SBRT, non-invasive)
- In this study, we evaluated two schedules of SBRT, single session and multi-session, for patients with limited secondary spread to the lung



TROG 13.01 SAFRON II: Trial Summary

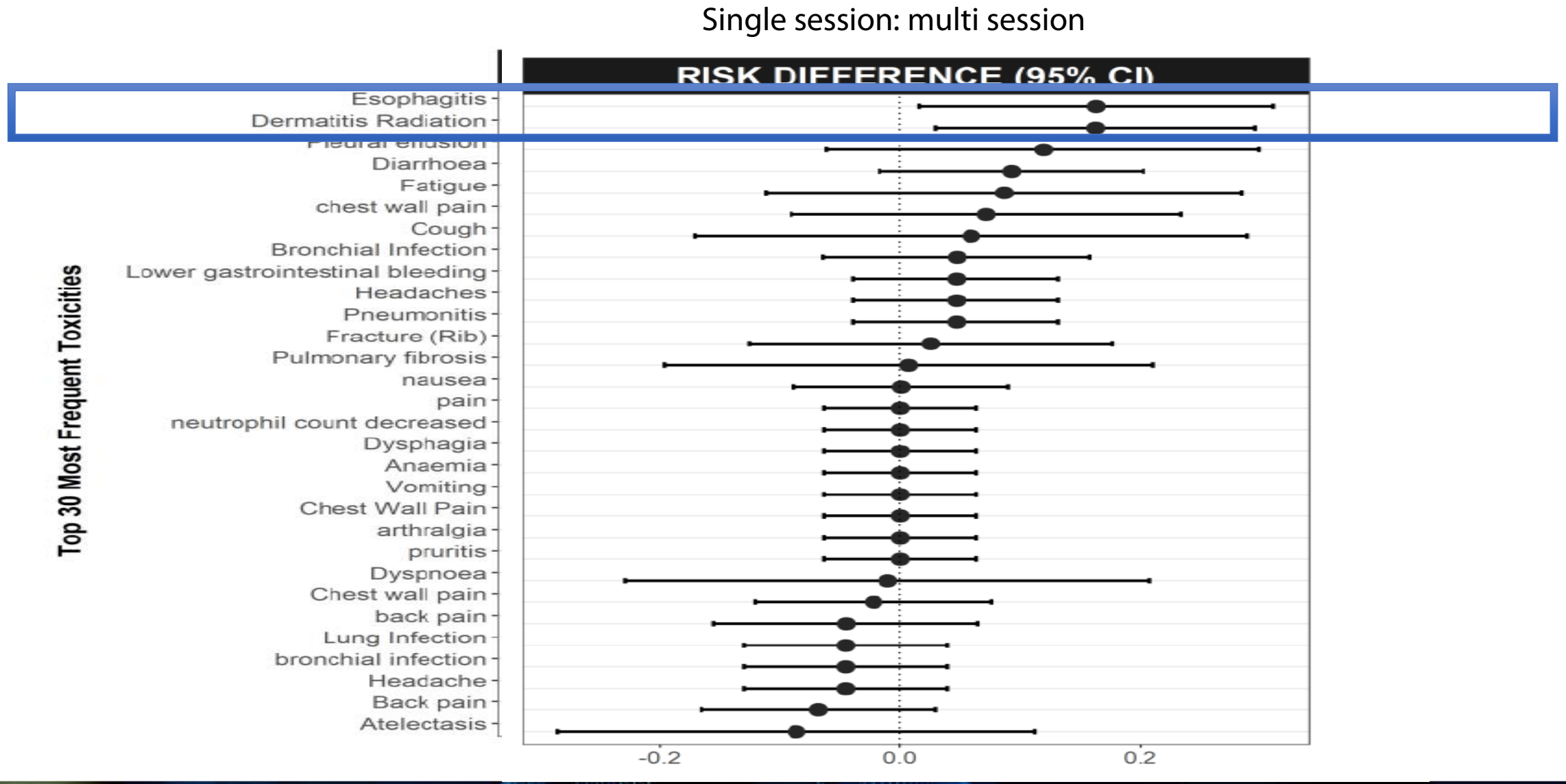


Key Inclusion: ≤3 secondaries to the lung from any non-blood malignancy, tumor size ≤ 5cm, peripheral lung location, all primary and extrathoracic disease treated

- Primary Endpoint: Severe side effects at 1 year
- Total sample size = 90 patients over 3 years (13 centers Australia and NZ), recruited 2015-2018

Side effects (any grade) and difference between arms

Higher swallowing symptoms and skin rash with multi-session SBRT



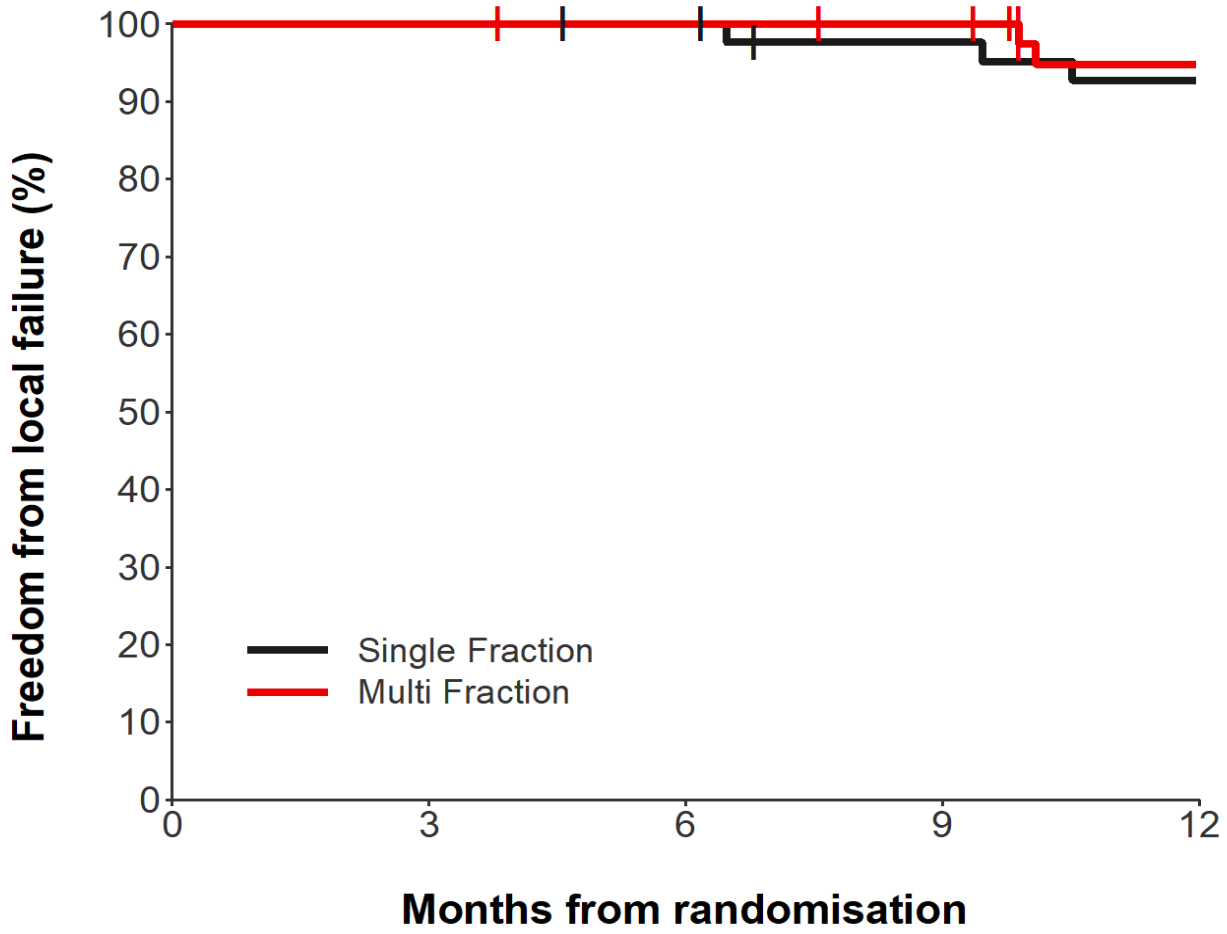
Primary Endpoint – high grade side effects within 1 year

- ARM 1 (single fraction) - There were two patients with grade 3 (*medical intervention*) events, both lasted < 3 months in duration, with no grade 4 (*life threatening*) or 5 (*fatal*) events.

- ARM 2 (four fraction) – There was one patient with a grade 5 event (pneumonitis within 3 months of SBRT, underlying ILD), with no grade 3 or 4 events.

- Grade 3+ toxicities related to treatment within 1 year
  - ARM 1 = 5% [80% CI: 1-14]
  - ARM 2 = 3% [80% CI: 0.3% - 10%]

Oncological Outcomes – Local Control

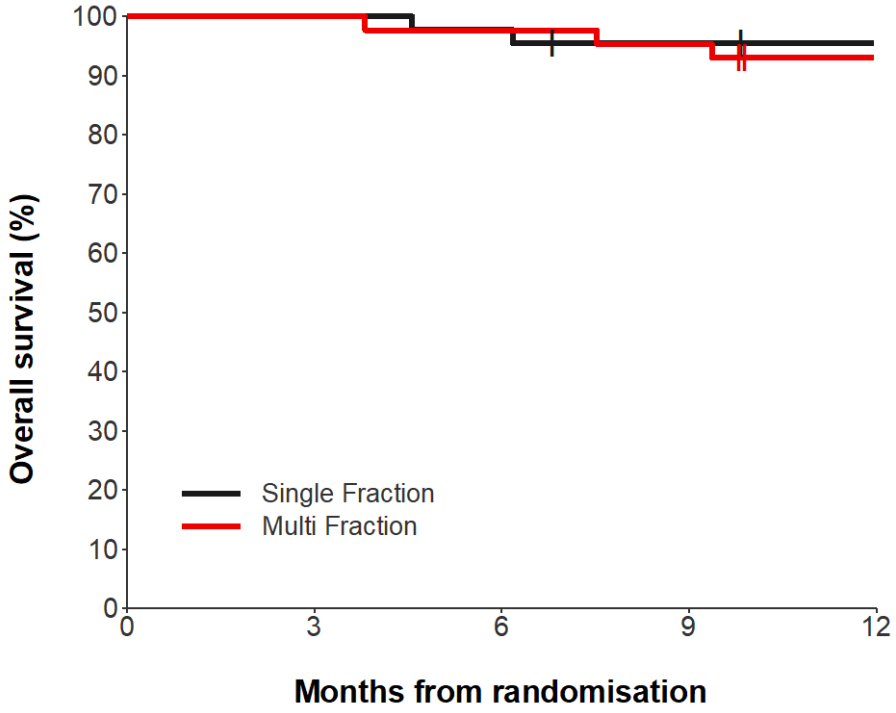


No. at risk					
Single Fraction	44	44	43	40	38
Multi Fraction	43	43	42	41	36

Freedom from local failure % (95% CI) at 12 months by arm

Single Fraction = 93% (79, 98)
Multi Fraction = 95% (81, 99)

Oncological Outcomes – Recurrence, Survival



No. at risk					
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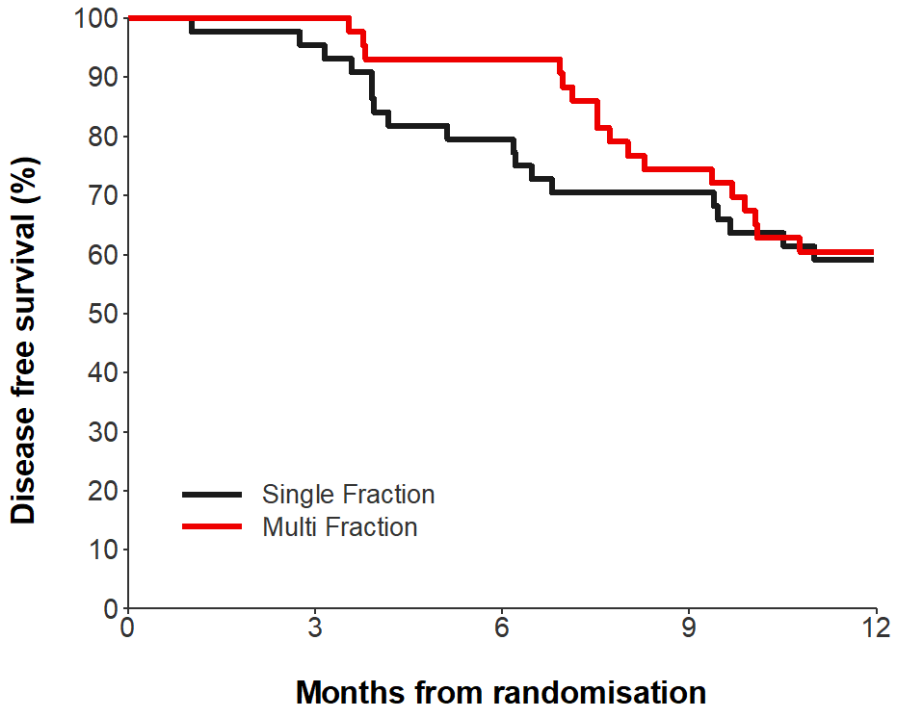

No. at risk					
Single Fraction	44	42	35	31	26
Multi Fraction	43	43	40	32	26

Kaplan-Meier estimates % (95% CI) at 12 months by arm

Endpoint	Single Fraction	Multi Fraction
Overall survival	95 (83, 99)	93 (80, 98)
Disease free survival	59 (43, 72)	60 (44, 73)

Conclusions

- Both single fraction (28Gy) and four fraction (48Gy) SBRT have acceptable toxicity for patients with 1-3 secondary cancer deposits in the lung

- Oncological outcomes from both approaches appear similar to 1-year

IMPACT - WHAT DOES THIS MEAN?

- Single session SBRT is convenient, non-invasive safe and appears effective to date for lung secondaries
- Maybe considered a one-stop, 'knockout punch'
- These findings may have implications for treatment selection in resource-constrained environments (such as the pandemic)